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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,654	02/22/2007	Michael Patrick Murphy	110199.405USPC	5113

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC  
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SEATTLE, WA 98104

EXAMINER
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HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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03/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/568,654	<b>Applicant(s)</b> MURPHY ET AL.	
	<b>Examiner</b> Raymond J. Henley III	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 88-127 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 88-111 and 113-127 is/are allowed.
- 6) ☒ Claim(s) 112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                               | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5 sheets</u> . | 6) <input type="checkbox"/> Other: ____.                                                |

**CLAIMS 88-127 ARE PRESENTED FOR EXAMINATION**

Applicants' Preliminary Amendment filed February 22, 2007 and Information Disclosure Statement filed April 24, 2009 have been received and entered into the application.

Accordingly, the application has been amended as indicated by Applicants. Also, as reflected by the attached, completed copies of form PTO-1449, (5 sheets), the cited references have been considered.

***Allowable Claims***

Claims 88-111 and 113-127 are deemed allowable. None of the cited references or any of the references discovered by the Examiner upon searching the appropriate data bases disclose or would have suggested the claimed subject matter.

***Claim Rejection - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 112 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of therapy utilizing the claimed compounds for reducing oxidative stress, does not reasonably provide enablement for the prophylaxis, (a.k.a. prevention), of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

***Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First***

***Paragraph***

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

“[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling.” (emphasis added).

Here, the objective truth of the statement that the claimed disease/condition, i.e., oxidative stress, can actually be prevented is doubted the term “preventing” is synonymous with the term “curing” and both circumscribe methods of absolute success. Because absolute success is not reasonably possible with most diseases/disorders caused by or associated with oxidative stress or oxidative stress itself, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as those presently disclosed in the specification, e.g., impaired cardiac function, (page 68 of the present specification, the specification, which lacks an objective showing that such diseases/disorders can actually be prevented, is viewed as lacking an enabling disclosure of the same.

Also, in order to accept that a particular compound is effective for the prevention of the disclosed diseases/disorders and those encompassed by the claims, one skilled in the art would have to be satisfied that a particular compound, or combination of compounds, could affect the pathoetiological factors associated with the inflammatory disease or condition whereby the disease or condition could be kept from ever becoming manifest.

Art Unit: 1614

It is noted that the term “prevent” does not necessarily mean that something is kept from ever occurring, but it is an interpretation that falls under the “broad and reasonable” standard for claim term interpretation as set forth in the MPEP at § 2111 and thus is proper.

Thus, because of the above reasons, the Examiner doubts the objective truth of the statement that the presently claimed active agents will prevent the claimed diseases/disorders and the Examiner has therefore satisfied the burden as set forth in *In re Marzocchi, Id.* for making a rejection under 35 U.S.C. § 112, first paragraph. The claims are therefore deemed properly rejected.

For the above reasons, claim 112 is deemed properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

Application/Control Number: 10/568,654

Page 5

Art Unit: 1614

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/  
Primary Examiner  
Art Unit 1614

March 19, 2010